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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,193	09/29/2005	Genevieve Andre-Fontaine	033339/292053	9098

826 7590 12/28/2007

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,193	ANDRE-FONTAINE ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,20-23 and 26-28* is/are pending in the application.

4a) Of the above claim(s) *7-16,20,23 and 26-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,21 and 22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of the invention of Group I, claims 1-6, and claims 21-22 (in part) in the reply filed on November 13, 2007 is acknowledged. The traversal is on the ground(s) that there is a special technical feature in common among the four groups, namely the peptide of SEQ ID NO:1, and that the X references cited in the Internatonal Search Report (ISR) create only a presumption that part of the invention is anticipated. This is not found persuasive because a peptide of SEQ ID NO:1 is not in common among the four groups. Neither the antibodies, the nuleic acids, nor the non-human transgenic organisms comprise a peptide of SEQ ID NO:1. There is no significant structural element or common property or activity shared by all of the claimed inventions, and the claimed inventions do not belong to the same recognized class of chemical compounds in the art to which the invention pertains. While the examiner agrees that the citation of an X reference in the ISR creates only a presumption that the claims lack a special technical feature, Applicants have not rebutted this presumption. Note that claims 7-25 are also indicated in the ISR as being anticipated by the cited references, and note the anticipation rejection set forth below.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-16, 20, and 26-28, and claims 21-22 (in part) are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on November 13, 2007.

2. The Sequence Listing filed July 23, 2007 is approved.

3. The abstract of the disclosure is objected to because it is greater than 150 words in length, and because it does not mention the therapeutic use of the inventive peptides, i.e. as a vaccine against Leptospirosis. Correction is required. See MPEP § 608.01(b).

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 21, and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the peptide represented by SEQ ID NO:1, the pharmaceutically acceptable salts of this peptide, the chemical derivatives of this peptide, and the peptide coupled to a carrier protein, does not reasonably provide enablement for homologs of this peptide, peptides comprising less than the 25 amino acid of SEQ ID NO:1, functional fragments of the peptide, and chemical analogs of the peptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. With respect to (1), the nature of the invention is a peptide vaccine for Leptospirosis. With respect to (2), Applicants

disclose at page 5, lines 28-30, of the specification that the state of the prior art is that whole bacteria are necessary to provide antigens. This contrasts with the instant claims, in which individual compounds are used to provide antigens. With respect to (3), the relative skill of those in the art is high. With respect to (4), the predictability of the vaccine art is relatively low. Applicants state at page 2, lines 7-10, that it is particularly difficult to combat Leptospirosis infections due to their bacteriological complexity and due to the diversity of animals which can be infected by the bacteria. With respect to (5), the breadth of the claims is relatively large. The claims embrace compounds in which up to 40% of the amino acids of the peptide of SEQ ID NO:1 are altered (i.e. in order to form homologs); in which ten or even more amino acids are deleted from the peptide of SEQ ID NO:1 (i.e. in order to form homologs or functional fragments); and in which any or all of the amino acids of the peptide of SEQ ID NO:1 have been replaced with their D enantiomers or with non-natural amino acids (in order to form chemical analogs). With respect to (6) and (7), Applicants' specification discloses working examples demonstrating the utility and enablement of the peptide of SEQ ID NO:1. However, Applicants' specification does not provide working examples, in vivo or in vitro or otherwise, for any other compound. Applicants' specification does not provide any structure-function relationship so that one of skilled in the art would reasonably know which portions of the peptide of SEQ ID NO:1 would have to be preserved in order to retain activity. With respect to (8), the quantity of experimentation necessary to use the entire claimed invention would be vast. Jones (U.S. Patent Application Publication 2003/0186887) shows that epitopes generally range in size from 3 to 10 amino acids. See paragraph [0008]. Accordingly, the changes in the peptide of SEQ ID NO:1 recited in Applicants' claims could easily alter or eliminate epitopes which are necessary for

activity. In the absence of any disclosed structure-function relationship, one skilled in the art would be limited essentially to random testing of all possible changes to the peptide of SEQ ID NO:1 in order to determine whether a particular compound can be used as a vaccine for Leptospirosis. Such random testing constitutes undue experimentation. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

5. Claims 1-6, 21, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear if claim 1, lines 2-4, should be interpreted as open or closed language. It is not clear if "the peptide" embraces larger peptides which comprise one or more amino acids in addition to those represented by SEQ ID NO:1. Note that dependent claim 3 recites that "The peptide" can comprise 30 amino acids, that dependent claim 5 permits the presence of as many 100 amino acids, and dependent claim 6 permits additional amino acids (in the form of a carrier protein) to be coupled to the peptide. If limited numbers of amino acids can be added to the peptide of SEQ ID NO:1 in the dependent claims, it would appear that an unlimited number of amino acids could be added to the peptide of SEQ ID NO:1 in the independent claim. At claim 1, lines 14-15, the "such as..." phrase makes it unclear as to whether the isosteric linkages are to be limited to the specifically recited linkages or not. It is suggested that the "such as..." phrase could be deleted from claim 1 and made the subject matter of a dependent claim 1. At claim 1, lines 18 and 21, it is not clear if "that" is referring to, e.g., the alkyl portions of the preceding groups, the alkyl or alkenyl or alkynyl portions of the preceding groups, the alkyl portion of the aralkyl group, etc. At claim 1, lines 19 and 22, it is not

clear if the limitation "comprising from 1 to 50 carbon atoms" is referring to, e.g., the alkyl portions of the preceding groups, the alkyl or alkenyl or alkynyl portions of the preceding groups, the alkyl portion of the aralkyl group, etc. Claim 1, lines 20-21, recites a limitation "alkyloxy, alkylthio, or alkylamino of the form -OR, -SR or -NHR, in which R represents an alkyl, alkenyl, alkynyl, or aryl chain or an aralkyl group". However, if this section of the claim is intended to define alkyloxy, alkylthio and alkylamino groups, it is contradictory to state that R can be alkenyl, alkynyl, aryl, or aralkyl. These groups are not alkyl groups. Claims 2-4, 6, and 21 refer to a "peptide as claimed in claim 1"; however, claim 1 is drawn to a compound, which may be any of many different peptides/homologs of peptides/derivatives of peptides/chemical derivatives of peptides. Note that only the peptide represented by SEQ ID NO:1 is named "peptide" in claim 1, and the limitations recited in claims 2-4 are inconsistent with a reference to just this single peptide. In claim 2, the "even more preferentially...", "preferably...", "even more favorably...", and "better still..." phrases make it unclear as to what % similarity the claim is limited. Claim 21 is indefinite because it refers to "a protein, or an antibody or a nucleic acid as claimed in claim 1"; however, claim 1 does not recite any of these compounds. Claim 21 is indefinite because it is not clear what constitutes a "pharmaceutically acceptable support". It is not clear if "support" should be interpreted differently than "carrier", and it is not clear if "support" should be interpreted as requiring a solid substance. The phrase is not used or defined in the specification.

6. Claims 4 and 5 are objected to because of the following informalities: At claim 4, line 2, and claim 5, line 3, "function" should be changed to "functional", consistent with the language used in the independent claim. Appropriate correction is required.

7. Claims 5 and 6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Assuming that claim 1, lines 2-4, should be interpreted as closed language, i.e. that the peptide consists of the 25 amino acids of SEQ ID NO:1, then dependent claims 5 and 6 are improper dependent claims, because there is no language or limitation in the independent claims which embraces coupling as many as 75 additional amino acids or a carrier protein to the peptide of SEQ ID NO:1 (or to its functional fragments, homologs, chemical analogs, or chemical derivatives).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 4, 6, 21, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 01/59123. (The examiner relies upon U.S. Patent Application Publication 2003/0124567 as a translation of the WO Patent Application '123. All citations in this rejection will be to the text of the translation.) The WO Patent Application '123 teaches a PPL protein of 32 kDa and comprising SEQ ID NO:7, whose residues at positions 153-177 are 100% similar to Applicants' SEQ ID NO:1. The WO Patent Application '123 also teaches immunogenic compositions comprising the protein, and the protein immobilized on solid supports. See, e.g., paragraphs [0024], [0067], [0070], [0086], and [0089], and claims 3 and 29 of the translation. Assuming that Applicants' claims do not exclude compounds in which

additional amino acids are added to either terminus of the peptide represented by SEQ ID NO:1 (see also the above rejection under 35 U.S.C. 112, second paragraph), the PPL protein of the WO Patent Application '123 anticipates Applicants' claimed compounds/peptides. With respect to instant claim 6, the fragments at residues 1-152 and 178-280 of the PPL protein of the WO Patent Application '123 correspond to Applicants' carrier protein.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

December 20, 2007